

AUG 13 2002

K 021599



96 Channel EEG
Headbox, PAGE 9 of 26
APRIL 29, 2002

Section E – 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR § 807.92.

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Regulatory Affairs

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Common Names: 96 Channel EEG Headbox

Classification Name: Electroencephalograph

Description: The 96 Channel EEG Headbox is a digital electroencephalograph that can also record pulse oximetry signals.

Intended Use: The 96 Channel EEG Headbox is intended to be used as an electroencephalograph: to acquire, store, and archive electroencephalographic signals with additional capabilities to record other physiological signals such as pulse oximetry.

Predicate Devices: Excel tech, Ltd. Neuro Works 128 Channel EEG
510(k)# K000919
Masimo SET Radical Pulse Oximeter
510(k)# K992340

Substantial Equivalence: The XLTEK 96 Channel EEG Headbox is substantially equivalent in safety and effectiveness to the Excel Tech, Ltd. NeuroWorks 128 Channel EEG and the Masimo SET Radical Pulse Oximeter.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Mr. John Mumford
President
Excel Tech, Ltd.
2568 Bristol Circle
Oakville, Ontario
Canada, L6H 5S1

APR - 9 2012

Re: K021599

Trade/Device Name: 96 Channel EEG Headbox, Model EMU96
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ, DQA
Dated (Date on orig SE ltr): April 29, 2002
Received (Date on orig SE ltr): May 15, 2002

Dear Mr. Mumford:

This letter corrects our substantially equivalent letter of August 13, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section D – Statement of Indications for Use

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510(k) Number (if known): K 021599

Device Name: 96 Channel EEG Headbox


Indications for Use: The 96 Channel EEG Headbox is intended to be used as an electroencephalograph: to acquire, store, and archive electroencephalographic signals with additional capabilities to record other physiological signals such as pulse oximetry.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ (Per 21§ CFR 801.109)

OR Over-The Counter Use ☐


(Division Sign-Off) (Optional Format 1-2-96)
Division of General Restorative
and Neurological Devices

510(k) Number K021599